## **Complete Summary**

#### **GUIDELINE TITLE**

American Society of Clinical Oncology technology assessment on the use of aromatase inhibitors as adjuvant therapy for women with hormone receptor-positive breast cancer: status report 2002.

## BIBLIOGRAPHIC SOURCE(S)

Winer EP, Hudis C, Burstein HJ, Chlebowski RT, Ingle JN, Edge SB, Mamounas EP, Gralow J, Goldstein LJ, Pritchard KI, Braun S, Cobleigh MA, Langer AS, Perotti J, Powles TJ, Whelan TJ, Browman GP. American Society of Clinical Oncology technology assessment on the use of aromatase inhibitors as adjuvant therapy for women with hormone receptor-positive breast cancer: status report 2002. J Clin Oncol 2002 Aug 1;20(15):3317-27. [53 references] PubMed

## **COMPLETE SUMMARY CONTENT**

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#### **SCOPE**

DISEASE/CONDITION(S)

Breast cancer

**GUIDELINE CATEGORY** 

Prevention Risk Assessment Technology Assessment

CLINICAL SPECIALTY

Obstetrics and Gynecology Oncology

#### INTENDED USERS

Physicians

## GUIDELINE OBJECTIVE(S)

To conduct an evidence-based technology assessment to determine whether the routine use of anastrozole or any of the aromatase inhibitors in the adjuvant breast cancer setting is appropriate for broad-based conventional use in clinical practice

#### TARGET POPULATION

Postmenopausal women with hormone receptor-positive, metastatic breast cancer

#### INTERVENTIONS AND PRACTICES CONSIDERED

- Use of third-generation antiaromatase agents (aromatase inhibitors/inactivators) as adjuvant therapy for hormone receptor-positive breast cancer:
  - Anastrozole (Arimidex)
  - Letrozole (considered but not enough clinical data on which to make a recommendation)
  - Exemestane (considered but not enough clinical data on which to make a recommendation)
- 2. Standard therapy with tamoxifen
- 3. Combination therapy of tamoxifen and anastrozole

#### MAJOR OUTCOMES CONSIDERED

- Breast cancer incidence
- Breast cancer-specific survival
- Overall survival
- Net health benefit

## METHODOLOGY

## METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Searches of Electronic Databases Searches of Unpublished Data

## DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Pertinent information from the published literature was retrieved and reviewed for the creation of this assessment. Computerized literature searches of MEDLINE (National Library of Medicine, Bethesda, MD) were performed through January 2002. Abstracts presented at American Society of Clinical Oncology (ASCO) annual meetings were also included. Key words/phrases included in the literature

search were: breast neoplasms, breast cancer, mammary neoplasms, randomized trials, phase, meta-analysis, aromatase, exemestane, anastrozole, letrozole, megestrol acetate, antiaromatase, Arimidex, triazole, Femara, and Aromasin. Limits included English language and human studies. In addition, the American Society of Clinical Oncology staff contacted representatives of American, Canadian, and European cooperative groups concerning ongoing adjuvant trials with aromatase inhibitors. Each of the three pharmaceutical companies that manufactures one of the commercially available aromatase inhibitors was also contacted and given an opportunity to provide the expert panel with unpublished data and the design of ongoing or planned trials.

#### NUMBER OF SOURCE DOCUMENTS

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

#### METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review with Evidence Tables

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The panel addressed the following questions to provide guidance to physicians and patients on the use of third-generation aromatase inhibitors in the adjuvant setting:

- 1. What are the overall clinical implications of the findings from the Arimidex (anastrozole) or Tamoxifen Alone or in Combination (ATAC) trial for the adjuvant treatment of postmenopausal women with operable breast cancer?
- 2. Are all aromatase inhibitors equivalent?
- 3. What is the role of aromatase inhibitors in women who have already started taking tamoxifen in the adjuvant setting?
- 4. Is there a role for an aromatase inhibitor in women who have completed a 5-year course of tamoxifen and are disease-free?
- 5. If an aromatase inhibitor is used in the adjuvant setting, for how long should it be administered?
- 6. What is the role of aromatase inhibitors in women who are premenopausal at the time of initiation of adjuvant hormonal therapy?
- 7. What is the role of aromatase inhibitors in women who are premenopausal at diagnosis and who experience interruption of ovarian function from chemotherapy?

- 8. What is the role of aromatase inhibitors in patients with ductal carcinoma-in-situ (DCIS)?
- 9. What is the role of aromatase inhibitors in women wishing to lower their risk of developing breast cancer?
- 10. What is the role of aromatase inhibitors in women whose tumors have negative hormone receptors?
- 11. What is the role of aromatase inhibitors in patients with certain biologic features, such as HER-2/neu positivity?
- 12. What is the role of aromatase inhibitors in patients with a relative or absolute contraindication to the initiation of adjuvant tamoxifen?
- 13. What is the role of aromatase inhibitors in patients who have developed hormone receptor-positive invasive breast cancer while taking either tamoxifen or raloxifene?

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

#### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

#### COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### METHOD OF GUIDELINE VALIDATION

Internal Peer Review

#### DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The conclusions of the panel were endorsed by the American Society of Clinical Oncology (ASCO) Health Services Research Committee (HSRC) and the American Society of Clinical Oncology Board of Directors.

## **RECOMMENDATIONS**

#### MAJOR RECOMMENDATIONS

The panel addressed the following questions to provide guidance to physicians and patients on the use of third-generation aromatase inhibitors in the adjuvant setting.

1. What are the overall clinical implications of the findings from the Arimidex (anastrozole) or Tamoxifen Alone or in Combination (ATAC) trial for the adjuvant treatment of postmenopausal women with operable breast cancer?

Panel Consensus. The panel is of the unanimous opinion that the results of the ATAC trial should be considered preliminary and that a 5-year course of tamoxifen remains the standard adjuvant hormonal treatment for women with hormone receptor-positive breast cancer. The panel looks forward to updated data from the ATAC trial and other trials addressing questions about the third-generation aromatase inhibitors in the adjuvant setting. The panel encourages appropriate patients to consider participation in ongoing randomized trials.

2. Are all aromatase inhibitors equivalent?

Panel Consensus. At the present time, the only available data using the third-generation aromatase inhibitors in the adjuvant setting are with anastrozole. The three commercially available agents seem to be generally comparable in the metastatic setting. While extrapolation from the ATAC trial to the use of other aromatase inhibitors is reasonable, direct data are lacking. Based on the extensive body of clinical trial data from the advanced disease setting, the effects of the three available aromatase inhibitors would be expected to be similar. At this time, however, the only evidence in the adjuvant setting involves anastrozole. Furthermore, the panel notes that closely related agents with similar mechanisms of action may have different toxicity profiles. For this reason, the panel considers anastrozole the preferred agent if an aromatase inhibitor is used in the adjuvant setting.

3. What is the role of aromatase inhibitors in women who have already started taking tamoxifen in the adjuvant setting?

Panel Consensus. There are currently no data to support substituting an aromatase inhibitor for tamoxifen as adjuvant therapy in a woman who has already started a course of tamoxifen. Outside of a clinical trial, women who are taking adjuvant tamoxifen and have not experienced significant side effects should continue tamoxifen therapy for a total of 5 years. Women experiencing intolerable side effects or who have developed a complication attributable to tamoxifen (i.e., thromboembolic event, persistent vaginal bleeding) may consider switching to an aromatase inhibitor, though the benefit of such a strategy is unproven and the optimal duration of such therapy is not known.

4. Is there a role for an aromatase inhibitor in women who have completed a 5-year course of tamoxifen and are disease-free?

Panel Consensus. Patients who have completed a 5-year course of tamoxifen and are free of disease should not receive an aromatase inhibitor unless such therapy is part of a clinical trial.

5. If an aromatase inhibitor is used in the adjuvant setting, for how long should it be administered?

Panel Consensus. Patients initiating aromatase inhibitor therapy in the adjuvant setting should be treated for at least 2 to 3 years based on the present experience from the ATAC trial. At this time, neither the efficacy nor the toxicity of a longer duration of therapy has been established. Clinicians and patients should expect to review the question of aromatase inhibitor duration as more data become available over the next several years.

6. What is the role of aromatase inhibitors in women who are premenopausal at the time of initiation of adjuvant hormonal therapy?

Panel Consensus. Aromatase inhibitors are contraindicated in premenopausal women with functioning ovaries. Such therapy has not been evaluated and is likely to be ineffective. The use of luteinizing hormone-releasing hormone (LHRH) agonists plus an aromatase inhibitor or oophorectomy plus an aromatase inhibitor in the adjuvant setting has not been studied and is not recommended outside of a clinical trial.

7. What is the role of aromatase inhibitors in women who are premenopausal at diagnosis and who experience interruption of ovarian function from chemotherapy?

Panel Consensus. The panel cautions against the use of adjuvant aromatase inhibitors in women who are premenopausal at the time of diagnosis and have experienced a disruption in ovarian function. The panel has particular concerns about the use of aromatase inhibitors in women who have a substantial probability of resuming ovarian function.

8. What is the role of aromatase inhibitors in patients with ductal carcinoma-in-situ (DCIS)?

Panel Consensus. Women with ductal carcinoma-in-situ should not receive an aromatase inhibitor outside of the context of a clinical trial.

9. What is the role of aromatase inhibitors in women wishing to lower their risk of developing breast cancer?

Panel Consensus. Women with an increased risk of developing breast cancer should not receive an aromatase inhibitor to decrease risk outside of a clinical trial.

10. What is the role of aromatase inhibitors in women whose tumors have negative hormone receptors?

Panel Consensus. Women whose tumors are known to be hormone receptornegative should not receive an aromatase inhibitor as adjuvant therapy.

11. What is the role of aromatase inhibitors in patients with certain biologic features, such as HER-2/neu positivity?

Panel Consensus. The panel recommends against the use of HER-2 status in making decisions about adjuvant hormonal therapy. The clinical data to support the use of HER-2 status in this setting are inadequate.

12. What is the role of aromatase inhibitors in patients with a relative or absolute contraindication to the initiation of adjuvant tamoxifen?

Panel Consensus. The panel considers it reasonable to initiate adjuvant hormonal therapy with an aromatase inhibitor in postmenopausal women who are thought to have a relative or absolute contraindication to adjuvant tamoxifen. Physicians and patients should carefully consider the significance of any relative contraindication in light of the proven benefits of adjuvant tamoxifen.

13. What is the role of aromatase inhibitors in patients who have developed hormone receptor-positive invasive breast cancer while taking either tamoxifen or raloxifene?

Panel Consensus. While recognizing the paucity of direct data, the panel considers it reasonable to use adjuvant hormonal treatment with an aromatase inhibitor in postmenopausal women with hormone receptor-positive cancers who had been taking tamoxifen or raloxifene at diagnosis and who are, therefore, considered clinically resistant to these antiestrogen agents.

CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations were based primarily on the results from large randomized phase II and phase III clinical trials, especially preliminary results from the Arimidex (anastrozole) or Tamoxifen Alone or in Combination (ATAC) trial. Testimony was also collected from invited experts and interested parties.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### POTENTIAL BENEFITS

- In patients with metastatic breast cancer, both anastrozole and letrozole demonstrated equivalent or improved efficacy when compared with tamoxifen, with similar or decreased toxicity. These studies have led to the approval of anastrozole and letrozole as first-line hormonal therapy for postmenopausal patients with metastatic breast cancer.
- Preliminary results from the Arimidex (anastrozole) or Tamoxifen Alone or in Combination (ATAC) trial showed a statistically significant improvement in disease-free survival favoring anastrozole compared with tamoxifen (Hazard

Ratio, 0.83; 95% Confidence Interval, 0.71 to 0.96; P=.013). There was no difference in disease-free survival between tamoxifen and the combination (Hazard Ratio, 1.02; 95% Confidence Interval, 0.88 to 1.18; P=.77).

## Subgroups Most Likely to Benefit:

- The panel considers it reasonable to initiate adjuvant hormonal therapy with an aromatase inhibitor in postmenopausal women who are thought to have a relative or absolute contraindication to adjuvant tamoxifen. Physicians and patients should consider the significance of any relative contraindication in light of the proven benefits of adjuvant tamoxifen.
- While recognizing the paucity of direct data, the panel considers it reasonable
  to use adjuvant hormonal treatment with an aromatase inhibitor in
  postmenopausal women with hormone receptor-positive cancers who had
  been taking tamoxifen or raloxifene at diagnosis and who are, therefore,
  considered clinically resistant to these antiestrogen agents.

#### POTENTIAL HARMS

- Preliminary results from the Arimidex (anastrozole) or Tamoxifen Alone or in Combination (ATAC) trial showed that hot flashes, weight gain of ≥ 10% at 2 years, vaginal bleeding, vaginal discharge, endometrial cancer, ischemic cerebrovascular events, and venous thromboembolic events were all significantly more common with tamoxifen than with anastrozole.
- Musculoskeletal disorders, fractures (all sites), and fractures in spine, hip, and wrist were all more common in women on anastrozole compared with tamoxifen. No data were provided concerning toxicity on the combination arm. The absolute incidence of most life-threatening complications (i.e., cancer, thromboembolic events) was quite low, and the absolute differences between the two arms were generally small. (Adverse events associated with tamoxifen and anastrozole in this trial are listed in Table 2 of the original guideline document.)

## Subgroups Most Likely to be Harmed:

The panel cautions against the use of adjuvant aromatase inhibitors in women who are premenopausal at the time of diagnosis and have experienced a disruption in ovarian function. The panel has particular concerns about the use of aromatase inhibitors in women who have a substantial probability of resuming ovarian function.

#### CONTRAINDICATIONS

## CONTRAINDICATIONS

Aromatase inhibitors are contraindicated in premenopausal women with functioning ovaries. Such therapy has not been evaluated and is likely to be ineffective. The use of luteinizing hormone-releasing hormone (LHRH) agonists plus an aromatase inhibitor or oophorectomy plus an aromatase inhibitor in the adjuvant setting has not been studied and is not recommended outside of a clinical trial.

## QUALIFYING STATEMENTS

#### QUALIFYING STATEMENTS

This technology assessment seeks to guide patients and physicians on the use of aromatase inhibitors in the adjuvant setting. Individual health care providers and their patients will need to come to their own conclusions, with careful consideration of all of the available data. The panel recognizes that there is an inherent tension between the desire to provide patients with the most up-to-date treatment approaches while at the same time exerting appropriate caution that such new treatments are adequately evaluated. The panel was influenced by the compelling, extensive, and long-term data available on tamoxifen. Overall, the panel considers the results of the Arimidex or Tamoxifen Alone or in Combination (ATAC) trial and the extensive supporting data to be very promising but insufficient to change the standard practice at the time of writing (May 2002). The panel recommends that physicians discuss the available information with patients, and, in making a decision, acknowledge that treatment approaches can change over time.

#### IMPLEMENTATION OF THE GUIDELINE

#### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

**IOM CARE NEED** 

Living with Illness

IOM DOMAIN

Effectiveness Patient-centeredness Safety

## IDENTIFYING INFORMATION AND AVAILABILITY

## BIBLIOGRAPHIC SOURCE(S)

Winer EP, Hudis C, Burstein HJ, Chlebowski RT, Ingle JN, Edge SB, Mamounas EP, Gralow J, Goldstein LJ, Pritchard KI, Braun S, Cobleigh MA, Langer AS, Perotti J, Powles TJ, Whelan TJ, Browman GP. American Society of Clinical Oncology technology assessment on the use of aromatase inhibitors as adjuvant therapy for women with hormone receptor-positive breast cancer: status report 2002. J Clin Oncol 2002 Aug 1;20(15):3317-27. [53 references] <a href="PubMed">PubMed</a>

#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2002 Aug 1

GUIDELINE DEVELOPER(S)

American Society of Clinical Oncology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Society of Clinical Oncology

**GUI DELI NE COMMITTEE** 

American Society of Clinical Oncology Aromatase Inhibitors Expert Panel

#### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Expert Panel Members: Eric P. Winer, MD (Chair), Dana-Farber Cancer Institute; Susan Braun, Susan G. Komen Breast Cancer Foundation (Patient/Advocate Representative); George P. Browman, MD, Hamilton Regional Cancer Centre; Harold J. Burstein, MD, PhD, Dana-Farber Cancer Institute; Rowan T. Chlebowski, MD, PhD, Harbor UCLA Medical Center; Melody A. Cobleigh, MD, Rush Presbyterian-St Luke's Medical Center; Stephen B. Edge, MD, Roswell Park Cancer Institute; Lori J. Goldstein, MD, Fox Chase Cancer Center; Julie Gralow, MD, University of Washington; Clifford Hudis, MD, Memorial Sloan-Kettering Cancer Center; James N. Ingle, MD, Mayo Clinic; Amy S. Langer, National Alliance of Breast Cancer Organizations (Patient/Advocate Representative); Eleftherios P. Mamounas, MD, Aultman Cancer Center; Judy Perotti, Y-ME National Breast Cancer Organization (Patient/Advocate Representative); Jan Platner, JD, National Breast Cancer Coalition (Patient/Advocate Representative); Trevor J. Powles, MD, PhD, The Royal Marsden Hospital; Kathleen I. Pritchard, MD, Toronto-Sunnybrook Regional Cancer Centre; Timothy J. Whelan, BM, BCh, MSc, Hamilton Regional Cancer Centre

## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the Working Group complied with American Society of Clinical Oncology (ASCO) policy on conflict of interest, which requires disclosure of any interest (financial or otherwise) that might be construed as constituting an actual, potential, or apparent conflict. Members completed ASCO's disclosure form and were asked to reveal ties to companies developing products that might potentially be affected by promulgation of the technology assessment report. Information was requested regarding employment, consultant status, stock ownership, honoraria, research funding, expert testimony, and membership on company advisory committees.

#### ASCO Aromatase Inhibitors Expert Panel

Eric P. Winer, MD, Chair, Dana-Farber Cancer Institute Boston, MA, Medical Oncology

A member on the Board of Directors or Advisory Committee of Pharmacia

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As Executive Director of NABCO, participates in relationships and projects with grant-makers having interests in AIs; included among these are unrestricted, educational grants from the following: AstraZeneca, Novartis, and Pharmacia

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Judy Perotti, Y-ME National Breast Cancer Organization Chicago, IL Patient/Advocate Representative No conflicts noted

Jan Platner, JD, National Breast Cancer Coalition Washington, DC Patient/Advocate Representative No conflicts noted

Trevor J. Powles, MD, PhD, The Royal Marsden Hospital Sutton, Surrey, United Kingdom Medical Oncology

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Medical Oncology

A consultant within the past 2 years for AstraZeneca and Pharmacia & Upjohn; received research funding from the National Cancer Institute of Canada Clinical Trials Group, contracted with Pharmacia & Upjohn and AstraZeneca; received honoraria directly in excess of \$2,000 per year or \$5,000 over a 3-year period from AstraZeneca and Pharmacia & Upjohn; member of Board of Directors or Advisory Committee for AstraZeneca and Pharmacia & Upjohn

Timothy J. Whelan, BM, BCh, MSc, Hamilton Regional Cancer Centre, Hamilton, Ontario, Canada Radiation Oncology No conflicts noted

#### **GUIDELINE STATUS**

This is the current release of the guideline.

#### **GUIDELINE AVAILABILITY**

Electronic copies: Available from the <u>American Society of Clinical Oncology</u> (ASCO) Web site.

Print copies: Available from American Society of Clinical Oncology, Health Services Research, 1900 Duke Street, Suite 200, Alexandria, VA 22314.

#### AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

 American Society of Clinical Oncology: Outcomes of cancer treatment for technology assessment and cancer treatment guidelines. J Clin Oncol 14:671-679, 1996.

Electronic copies: Available from the <u>American Society of Clinical Oncology</u> (ASCO) Web site.

Print copies: Available from American Society of Clinical Oncology, Health Services Research, 1900 Duke Street, Suite 200, Alexandria, VA 22314.

## PATIENT RESOURCES

A document titled "Technology assessment: aromatase inhibitors for early breast cancer" is available from the <u>American Society for Clinical Oncology (ASCO) Web</u> site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

#### NGC STATUS

This NGC summary was completed by ECRI on February 27, 2003. The information was verified by the guideline developer on March 14, 2003.

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Date Modified: 11/8/2004

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